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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,127	04/16/2004	Naoyuki Fukuchi	251865US0CONT	7991
22850	7590	04/08/2009		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER GABEL, GAIENE	
			ART UNIT 1641	PAPER NUMBER
			NOTIFICATION DATE 04/08/2009	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/825,127	<b>Applicant(s)</b> FUKUCHI ET AL.	
	<b>Examiner</b> GAILENE R. GABEL	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 31 and 35-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31 and 35-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Amendment Entry***

1. Applicant's amendment and response, filed February 26, 2009 is acknowledged and has been entered. Claims 21-30 have been cancelled. Accordingly, claims 31 and 35-39 are pending and are under examination.

### ***Withdrawn Rejections***

2. All rejections not reiterated herein, have been withdrawn.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 31 and 35-39 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-14 of U.S. Patent No. 6,878,811 in view of Lopez et al. (Cloning of the alpha chain of human platelet glycoprotein Ib: a transmembrane. Proc. Natl. Acad. Sci. USA 84: 5615-5619 (December 28, 1987)) or Ruggeri et al. (WO 93/16712). Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions recite a chimeric protein and a kit comprising the chimeric protein which consists of an Fc region of immunoglobulin molecule fused at its amino terminus to a partial protein of glycoprotein Ib $\alpha$  chain at its carboxyl terminus, wherein the partial proteins consists of amino acid residues 1-319 of GPIb $\alpha$ , or amino acid residues 1-293 of GPIb $\alpha$ , or amino acid residues 251-285 of GPIb $\alpha$ , all of which consist of the von Willebrand binding site of GPIb $\alpha$ .

US Patent 6,878,811 differs in failing to recite that the partial protein consists of amino acid residues 1-319 of GPIb $\alpha$ , amino acid residues 1-293 of GPIb $\alpha$ , and amino acid residues 251-285 of GPIb $\alpha$ .

Lopez et al. teach a partial protein which consists of amino acid residues 1-319 of human glycoprotein Ib chain. According to Lopez et al., the partial protein contains therein the von Willebrand factor binding site of glycoprotein Ib $\alpha$  chain (Abstract, p. 5615, 1<sup>st</sup> and 2<sup>nd</sup> col., and Figure 2).

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Ruggeri et al. disclose antithrombotic polypeptides based upon partial proteins (fragments) of glycoprotein Ib $\alpha$  (GPIb $\alpha$ ). In as far as the actual binding site for vWF, Ruggeri et al. specifically provide that the actual binding site for vWF on GPIb-IX receptor is localized within and consists of the region of GPIb $\alpha$  chain comprising amino acid 1-293 residues of the GPIb $\alpha$  chain. The polypeptides are modified and patterned on fragments of GPIb $\alpha$  that comprise all or part of the binding domain of GPIb $\alpha$  for von Willebrand Factor (vWF). See page 9, lines 3-24; page 12, lines 24-31; page 13, lines 15-39; and page 16, lines 15-19.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to specifically design the partial protein of GPIb $\alpha$  to consist of any one of amino acid residues 1-319 of GPIb $\alpha$ , amino acid residues 1-293 of GPIb $\alpha$ , or amino acid residues 251-285 of GPIb $\alpha$  for incorporation with the Fc region of an immunoglobulin for binding with vWF because both Lopez and Ruggieri specifically taught that amino acid residues 1-319, 1-293, or 251-285 contain the binding site for vWF. It also would have been obvious to incorporate the chimeric protein into a kit format for detecting binding of VWF, because kits are well known and conventional in the art for their recognized advantage of convenience and economy.

#### ***Terminal Disclaimer***

4. The terminal disclaimer filed February 26, 2009 to overcome the Nonstatutory Obviousness Double Patenting Rejection is improper because attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or

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agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c). Specifically, Dr. Vincent Shier is not listed as attorney of record in the Oath or Declaration. A statement of Power of Attorney is required.

5. No claims are allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAIENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday, Tuesday, Thursday, 5:30 AM to 4:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/  
Primary Examiner, Art Unit 1641

April 2, 2009